DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-922/S-021

Wyeth Pharmaceuticals, Inc.
Attention: Valerie Heisterkamp
Manager, Worldwide Regulatory Affairs
PO Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Heisterkamp:

Please refer to your supplemental new drug application dated November 23, 2004, received November 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lodine (etodolac) 200 mg and 300 mg capsules, and 400 mg and 500 mg tablets.

We acknowledge receipt of your submission dated November 23, 2004.

This supplemental new drug application incorporates the labeling changes recommended in the approvable letters sent for the following:

1. S-017, submitted on October 7, 1998 to provide for NSAID class labeling, approvable letter sent May 21, 2003
2. S-018, submitted on August 20, 1998, to provide for the inclusion of a Geriatric Use section to the package insert, approvable letter sent May 21, 2004
3. S-019, submitted on June 13, 2001, to provide for changes to the **PRECAUTIONS, Drug Interactions, *Warfarin*** subsection of the label and to the **ADVERSE REACTIONS** section of the label, approvable letter sent May 21, 2003 and June 3, 2004
4. S-020, submitted on November 25, 2003, to provide for the inclusion of "toxic epidermal necrolysis" under the **ADVERSE REACTIONS, Incidence Less Than 1%-Probably Causally Related,** Skin and appendages subsection of the label, approvable letter sent June 3, 2004.

This supplemental new drug application also provides for draft labeling that incorporates the changes specified in the May 21, 2003 and June 3, 2004 approvable letters as well as proposed modifications that serve to harmonize the package insert with Lodine® XL and/or class labeling.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to enclosed labeling.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies

of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 18-922/S-021**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. Jane A. Dean, RN, MSN, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, MD
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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